IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JULIE DELANEY and
WILLIAM DELANEY

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

CIVIL ACTION No. 05-CV-10241 (MLW)

PLAINTIFFS' MEMORANDUM IN SUPPORT OF OPPOSITION TO DEFENDANT ELI LILLY'S MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

Diethylstilbestrol ("DES"), a mid-20th century fertility nostrum, has been banned by the Food and Drug Administration, recalled by the manufacturers and branded a carcinogen and teratogen by the World Health Organization, the National Institutes of Health (NIH), the American College of Obstetrics and Gynecology, and every health organization devoted to reproductive medicine. See Affidavit of Aaron M. Levine, Esq. Regarding Authentication of Documents ("Levine Aff."), Apps. 1 & 4. Even Defendant Lilly admits it was a mistake. See App. 2, attached to Levine Aff.; see also *CDC Resource Focuses on DES Exposure*, 289 J. Amer. Med. Assn. 1624 (2003); *DES: The Complete Story*, Orenberg, St. Martin Press 1981, *The Greatest Experiment Ever Performed On Women*, Seaman, Hyperion Press, (2003); *Daughters At Risk: A Personal DES Story*, Doubleday (1981)). The drug was sold to five to ten million women as a universal remedy to produce plump and healthy babies even though it never worked.[1] See W.J. Dieckmann, M.D., et al., *Does the Administration of Diethylstilbestrol During Pregnancy Have Therapeutic Value?* 66 Amer. J. of Ob. and Gyn. 1062, 1074 (1953), see App. 5, attached to Levine Aff. The Defendants failed to conduct a single test to investigate the DES effect on the forming female daughter even though they knew since the 1940s of reports in the literature that estrogen and DES in high doses stunted the reproductive organs of the exposed daughter in animals. See Apps. 3 & 4, attached to Levine Aff.

1 In 1968, the National Academy of Sciences in its review of the effectiveness of DES for the purpose of preventing threatened or habitual abortion found that effectiveness cannot be demonstrated by the literature or its own experience. See Hearing Before the Subcommittee on Government Operations 92nd Congress Nov 11, 1971, P. 77. At this time Lilly was asked by the F.D.A. to provide evidence that DES was effective and failed to provide any such information.

Julie Delaney is entitled to stitch together numerous facts thereby creating a quilt work, which, in its totality, provides proof of product identity:

1) Her mother, Barbara O'Leary, independently identifies the unique Lilly white, cross-scored pill out of a photographic line-up. See Deposition of Barbara O'Leary, p. 29-30, 37-38, 46, App. 19, attached to Levine Aff.

2) The mother's descriptions of the size, marking, and shape of the pill fits Lilly's DES tablet exclusively. See Lilly Pill Photo, App. 10, attached to Levine Aff. No other manufacturer made a white, cross-scored, round, DES tablet without imprint besides Eli Lilly. Lilly's only alibi, the Bristol Myers Squibb DES, was a 100 mg, cross-marked tablet with the word "Squibb" imprinted on one side of it. See Bristol-Myers Squibb Pill Photo ("Squibb Pill"), App. 8 and Sparr Statement, App. 7, paragraph 9, attached to Levine Aff. This does not match the pill the mother identified with no imprint and a lower dosage pill contained in the medical records, and disqualifies Squibb as a suspect. See Deposition of Philip Sullivan, M.D., with attached prenatal records of Barbara's O'Leary's 1970 pregnancy, App. 14, attached to Levine Aff. Furthermore, Squibb disputes that they even made or marketed a white, cross-scored pill. See Response No. 5 of Defendant Bristol-Myers Squibb Company's Response to Plaintiff's First Set of Interrogatories and Response to Request for Production of Documents in Gilbert v. Eli Lilly & Co., No. 05-CA 9623 (Super. Ct. District of Columbia, August 1, 2006), ("Defendant's Response to Interrogs."), App. 25, attached to Levine Aff.

3) An eminent and knowledgeable Boston pharmacist, Mr. Harold Sparr, testified that the Lilly's DES was exclusively ubiquitous in the Boston/Hingham Area in

the late 1960's and early 1970's. See Sparr Statement, App. 7, attached to Levine Aff.

4) A national pharmacy expert and Lilly District Manager state the mother's description of the DES pill fits Lilly's only, and that the Lilly's DES constituted the lion's share of the Boston DES market. See Corrected Statement of Philip J. Cafferty ("Cafferty Statement"), App. 12, attached to Levine Aff.

5) Lilly admits it controlled the DES market. See Testimony of Thomas Carney, Vice President of Eli Lilly & Co., *Hearing Before the Committee on Interstate and Foreign Commerce House of Representatives*, 86th Congress, Second Session (1960), ("Carney Testimony"), attached as App. 15 to Levine Aff.

6) Defendant Lilly, a multi-billion dollar company, with its thousands of pharmacy detailmen and voluminous records, has not come up with a shred of evidence that any other brand was available at the relevant pharmacy, or that any other brand made a small, round, white cross-scored DES tablet without imprint. In response to discovery, Defendant Lilly has no alibi. See Def. Ans. to Int. ¶2 and 3, App. 6, attached to Levine Aff.

7) The 1969 Physician's Desk Reference ("PDR"), (the authority on prescription medication for physicians), cited and indicated only Lilly's DES, App. 20, attached to Levine Aff.

8) A scientific study conducted by Boston University concluded that Lilly had 94% of the Boston DES Market. See Report of Hannelore Vanderschmidt ("Vanderschmidt Report"), App. 21, attached to Levine Aff.

II. PLAINTIFFS' RESPONSE TO DEFENDANT'S STATEMENT OF MATERIAL FACTS

1. Admitted.

2. Denied. Plaintiff and her counsel, through discovery and investigation, have gathered various positive evidences from her mother's photographic identification, deposition testimony, as well as the local pharmacist's testimony that Eli Lilly manufactured the DES pills that caused her reproductive injuries. See O'Leary Dep., pgs. 15, 17, 21, 24, 26-31, 37-38, 46, attached to Levine Aff.; Statement of Harold B. Sparr, R.PH ("Sparr Statement"), App. 7, attached to Levine Aff.

3-5. Admitted.

6. Denied. Mrs. O'Leary, who shopped at Hingham Pharmacy, which was located in Hingham, Massachusetts, visually identified the white, cross-scored Lilly DES pill from a photographic lineup, which included various pills of different sizes and colors from a variety of brands. See O'Leary Dep, pgs. 37-39, App. 19; Photograph of Lilly's DES, App. 10, attached to Levine Aff. In addition, Lilly's DES is the only white cross-scored DES pill without any other markings available in Boston/Hingham during 1970. See Photograph of Lilly's DES, App. 10; Sparr Statement, App. 7, attached to Levine Aff. Lilly cornered 94% of the DES market in Boston. See Harold B. Sparr Study ("Sparr Study"), App. 11, attached to Levine Aff.; Vanderschmidt Report, App. 21, attached to Levine Aff. No other company had control of the DES market in the 60's and early 70's. See Sparr Statement, App. 7; Cafferty Statement, App. 12, attached to Levine Aff. Most other companies were only local and regional. For example, Person & Covey only sold DES to California, Arizona, and Nevada, but never in Massachusetts. See Deposition of Lorne Person, Sr., in Nierenberg v. Abbott Lab. et al., Civil Action No. 2958 (Ct. Common Pleas Phil. Cty., Jan. Term 1993, dated April 22, 1994) ("Person Dep."), App. 13, attached to Levine Aff.

7. Admitted.

8. Admitted. Based on numerous other sources, as stated above, identifying Lilly as the culprit in this case, Plaintiffs withdraw any reliance on the Statement of James Della Volpe.

9. Denied. See No. 8.

10. Denied. The companies listed in the Red and Blue Book, in fact, were not national manufacturers as the Defendant implies - but were generic, local repackagers and bottlers. Nowhere does the Red or Blue book identify or designate the listed companies as manufacturers. The great majority of the listings consist of local rebottlers who sold locally and regionally in non-Boston limited areas of America and who manufactured nothing. See Sparr Statement and Sparr Study, App. 7 and 11, attached to Levine Aff. The Red Book and Blue Book are technical catalogues of sellers and not accurate representations of the Boston or national DES market, nor do they supply any information as to what brand of DES was on the shelves of Hingham Pharmacy in 1970. See Sparr Statement and Sparr Study, App. 7 and 11. It is inconceivable that any pharmacist would keep 60 brands of the same generic drug on their shelves (but in actuality, there were only 6-8 name brand national manufacturers, not 60 as alleged by the Defendant, see Plaintiff's Counter Statement of Facts in Issue No. 16).

11. Denied. The Bristol-Myers' Squibb DES pill was "Stilbetin", not Stilbestrol, had the emblem word "Squibb" imprinted on the pill, and it is disputed by Squibb, that their DES pill was even cross-cored. See Squibb Pill Photo, App. 8, and App. 25, attached to Levine Aff.

12. Denied. There is evidence that only Lilly made the tablet identified by the mother. See Sparr Statement and Sparr Study, App. 7 and 11, attached to Levine Aff. Mrs. O'Leary clearly and definitively testified that there were no markings aside from the cross-score on the diethylstilbestrol pill she took while she was pregnant with the Plaintiff. See O'Leary Dep., pgs. 29-30, 46, App. 19. Also, Squibb's white cross-scored pill was 100mg, and the mother's medical records showed a lower dosage (starting at 12.5 mg, which she broke in quarters) making it impossible for her to ingest Squibb's pill. (See prenatal records of Barbara O'Leary, App. 14, deposition of O'Leary, p. 29, attached to Levine Aff.) Squibb even disputes they made or marketed a cross-scored pill. See Defendant's Response to Interrogs., App. 25, attached to Levine Aff. Squibb's Stilbetin, a pill that does not match the mother's descriptions, cannot exculpate Lilly.

13. Admitted.

Plaintiffs' Counter Statement of Facts

14. Philip Cafferty, *a Lilly Detailman and District Manager*, has testified that Lilly's DES fits the mother's description and was the only brand available in Massachusetts. See Cafferty Statement, pg. 5., App. 12, attached to Levine Aff.

15. The President of the Massachusetts Board of Registration in Pharmacy, who has worked in Boston/Hingham area for the last fifty-six years and is familiar with the region where Plaintiff's mother purchased the DES in 1969 states that: "Lilly virtually owned that DES market" in Boston/Hingham, Massachusetts and "if a woman was dispensed DES as a white cross-scored tablet in Boston in 1970, she would have received Lilly's Diethylstilbestrol..." See Sparr Statement, App. 7, attached to Levine Aff.

16. Eli Lilly and Company dominated the DES market in pregnancy sizes throughout the country and made a DES pill fitting the mother's descriptions. See Cafferty Statement, App. 12 and Sparr Statement, App. 7, attached to Levine Aff. That is, Lilly is the only manufacturer that made a white, cross-scored tablet without imprint that was popularly used to treat accidents of pregnancy in the 1960's. See Sparr Statement, App. 7, Sparr Study, App. 11; Cafferty Statement, App, 12; Zhang Affidavit, 9; Lilly DES Photo, App. 10, all of which are attached to Levine Aff. Most other companies were generics and distributed locally and regionally. See Sparr Statement and Sparr Study, App. 7 and 11, attached to Levine Aff.

17. Defendant Lilly admits it held the lions-share of the DES market and produced 75% of the DES sold. See Carney Testimony, App. 15, attached to Levine Aff.

18. Mrs. O'Leary clearly and definitively testified that there were no markings aside from the cross-score on the diethylstilbestrol pill she took while she was pregnant with the Plaintiff. See O'Leary Dep., pgs. 29-30, 46, App. 19, attached to Levine Aff. Also, Squibb's white cross-scored pill was 100mg, and the mother's medical records showed a lower dosage (starting at 12.5 mg, which she broke) making it impossible for her to ingest Squibb's pill. (See medical records of Barbara O'Leary, App. 14, App. 19, pg. 29, attached to Levine Aff.) Squibb's Stilbetin, a pill that does not match the mother's descriptions, cannot exculpate Lilly.

ARGUMENT

III. DEFENDANT HAS NOT MET ITS SUMMARY JUDGMENT THRESHOLD

In order to prevail, Lilly must present to the court a scenario and setting which precludes the possibility that a reasonable juror could find in favor of the plaintiffs. The

DES case of Shields v. Eli Lilly & Co., which centered on sufficiency of proof in opposing summary judgment, sets the bar:

> In a world short of absolutes, the jury is called upon to process less than perfect evidence. Litigants may not offer speculations or slight possibilities in support of their claims; but neither are they limited to offering only the incontrovertible. The jury's function contemplates that evidence may be less than indubitable... Every conceivable alternative theory of causation need not be extirpated by a litigant seeking the jury's decision.

Shields v. Eli Lilly & Co., 895 F.2d 1463, 1467 (D.C. Cir. 1990).

> Summary judgment should be granted only where the court, viewing the evidence in the light most favorable to the non-moving party, determines that no genuine dispute of material fact exists.... Facts are 'material' if they possess 'the capacity to sway the outcome of litigation under the applicable law.'

Great Northern Ins. Co. v. Paino Associates, 364 F.Supp.2d 7 (D.Mass. 2005).

> In examining the sufficiency of affidavits filed in connection with the motion, the affidavits of the moving party are strictly construed and those of his opponent liberally construed, and doubts as to the propriety of granting the motion should be resolved in favor of the party opposing the motion.

D'amico et al. v. Board of Medical Examiners et al., 520 P.2d 10 (CA 1974).

> The 'significantly probative' test does not require the nonmoving party to discredit every conceivable alternative theory of causation. As this court noted in Elliott v. Michael James, Inc., 507 F.2d 1179 (D.C. Cir. 1974), 'there is no requirement that the circumstances, to justify the inferences sought, negative every other positive or possible conclusion.' To be significantly probative, evidence need only be sufficient to permit a reasonable juror, indulging all reasonable inferences, to find that the party proved the element at issue....

Shields, 895 F.2d at 1465.

As a threshold requirement in a products liability case, identification of the injury-causing product must be established only by a preponderance of the evidence. Caldwell v. Fox, 231 N.W. 2d 46 (Mich. 1975). In the recent DES case of Dunseth v. Eli Lilly &

Company, No. 03-CV-02123 (D.D.C. Memorandum Opinion December 16, 2005), Judge Reggie Walton of the United States District Court for the District of Columbia recognizing that summary judgment "is a drastic remedy, [and therefore] courts should grant it with caution so that no person will be deprived of his or her day in court to prove a disputed material factual issue", ruled that a plaintiff's mother's DES pill description, coupled with the affidavit of a local pharmacist (although not in the relevant store) identifying Lilly as the manufacturer of the drug in question, created "an inference of probability" sufficient to defeat summary judgment. See Dunseth at *3 & *8 (quoting Zimmer v. Celotex Corp., 549 N.E.2d 881, 883 (Ill. App. Ct. 1989), App. 16, attached to Levine Aff.

Lilly has been repeatedly judicially rebuffed in its quest for summary judgment on product identification in DES, in cases with less evidence than presented here. Less than nine months ago, Judge Henry H. Kennedy of the Federal Court in the District of Columbia, denied Lilly's summary judgment attempt on product identification, stating that: "The court is not only required to believe the competent evidence of the [Plaintiff], but must also grant all reasonable inferences in her favor". See Gassman v. Eli Lilly, No. 03-02592, mem. op. at *16 (D.D.C. Dec. 29, 2005), App. 17, attached to Levine Aff. On March 16, 2006, Judge Urbina again denied Lilly's summary judgment motion on product identification. See Clayton v. Eli Lilly, No. 04-1363, slip. op. (D.D.C. March 16, 2006), attached as App. 18 to Levine Aff. ("In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true").

IV. PLAINTIFFS PRESENT AMPLE EVIDENCE TO PROVE THAT LILLY'S DES WAS THE CULPRIT

In Kramer v. Weedhopper of Utah, Inc., 490 N.E.2d 104 (Ill. App. Ct. 1986), the court of appeals reversed the trial court's holding that 9-1 odds were not sufficient to create a fact issue as to identification. In Kramer, plaintiff was injured when his ultra light aircraft crashed. He sued the company that provided 90 percent of the bolts used to assemble the airplane. Specifically the appellate court said:

> the dispute centers on whether the fact that defendant supplied 90 percent of the bolts used by Weedhopper is sufficient circumstantial evidence to avoid entry of summary judgment. Circumstantial evidence consists of factors or circumstances which give rise to a reasonable inference of the truth of the underlying fact. The focus must then be on what quantum of evidence is sufficient for an inference to be reasonable. This measure has eluded specific standardization and enumeration. Generally the test of reasonableness resolves itself into a question of probability: is the inferred occurrence more probable than not, or is it merely possible. In the instant action there is evidence that
>
> 1) defendant supplied 90 percent of the relevant bolts
> 2) defendant supplied bolts to meet the general demand
> 3) other companies provided bolts only when necessary.
>
> Hughes Aviation was merely a 'possible source' and plaintiff need not, at summary decision, disprove that possibility. Defendant was allegedly the most probable cause of plaintiff's injury. The defects in plaintiff's proof are such that affect the weight, not whether there is a genuine matter triable question of fact.

Kramer, 490 N.E.2d at 107.

Drayton v. Jiffee Chemical Corp., 395 F. Supp. 108 (N.D. Ohio 1975), *aff'd* on issue of product identification, 591 F.2d 352 (6th Cir. 1978), highlights the importance of providing corroborative exclusion evidence. In that case, a minor plaintiff suffered severe burns from spilled liquid drain cleaner. The container was never recovered. However, plaintiff presented three witnesses to establish that the drain cleaner which caused plaintiff's injury bore defendant's label 'Liquid Plumr'. Drayton, 591 F.2d at

356. Plaintiff's landlady testified that she had bought a bottle of 'Liquid Plumr' over one year prior to the accident, plaintiff's mother testified that she saw the bottle with the label 'Liquid Plumr' soon before the accident and plaintiff's father testified that he also saw the label prior to the accident. Defendant introduced expert testimony that both the use of the drain cleaner as described by plaintiff's father and the type of injury caused were consistent with a different drain cleaner. In finding that plaintiff's evidence was sufficient to establish product identification, the court looked at the totality of the evidence and held that for an inference to prevail that defendant's product was not involved, the court would have to find the unequivocal testimony of all plaintiff's witnesses to be incredible. That court, as this court should, was unwilling to make such a finding. Id.

Finally, Liggons v. Roehm GMBH, 1993 US App Lexis 1335, *aff'd* (unpublished opinion) 983 F.2d 1067 (E.D. Mich 1993) reflects on statistical evidence and supports product identification with less than a 95 percent confidence level. In Liggons, plaintiff sued a handgun manufacturer after she was struck by a bullet fired from a handgun that had fallen to the ground. One of plaintiff's experts testified, in part, that there were 83 derringers that possessed the same characteristics shown on the bullet, and seventy-five of those were manufactured by defendant. The court noted that although plaintiff had not established to a certainty that defendant had manufactured the handgun that caused the injury, they had produced sufficient evidence to raise a jury question. Liggons, 1993 US App Lexis 1335, *1. The court commented that "plaintiff produced evidence 'tending to show' that defendants manufactured the gun in question." These authorities put the "blue

bus" case cited by the Defendant at page 5 of their memorandum in its proper perspective.

A. Plaintiffs' Evidence Matches Lilly's DES Exclusively

Lilly's attempts to reduce and generalize Mrs. O'Leary's testimony to the blue bus case lacks accuracy and relevance.[2] See Def. Mem. at 7; Smith v. Rapid Transit, Inc., 58 N.E.2d 754-5 (Mass. 1945). It is uncontroverted that Plaintiff Julie Delaney's mother was prescribed and ingested diethylstilbestrol pills in order to prevent miscarriage while pregnant with Ms. Delaney in 1969-1970. See O'Leary Dep., pg. 26, App. 19, attached to Levine Aff. She recalls the pill she ingested: (a) was called Stilbestrol (b) small, (c) round, (d) white, (e) with a cross on it, (f) was given to prevent a miscarriage, and (g) had no other writing or markings on the pill. See O'Leary Dep., p. 24, 26, 29-30, 46, App. 19, attached to Levine Aff. Mrs. O'Leary visually identified and picked out the Lilly DES pill as the one she ingested from photographs of numerous different DES pills. See O'Leary Dep., p. 37, App. 19; Lilly DES Photo., App. 10, attached to Levine Aff.

Lilly's 25mg DES pill solely and exclusively fits those exact descriptions. See 1969 PDR, App. 20 and Photograph of Lilly's 25mg bottle and DES pill, App. 10,

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[2] Even Professor Nesson, the creator of the Blue Bus hypothetical, explained: "At some point, high probability alone is sufficient to produce an acceptable verdict. In the blue bus hypothetical ... evidence indicating a 55% likelihood that the plaintiff should recover presents a problem, whereas evidence indicating a 95% likelihood might not. Reaching a conclusion involves putting doubt aside. The difficulty of doing so will vary with the intensity of the doubt, the degree to which we are concerned about making a mistake, and the rationalizations we have to help us conclude." The Delaneys, in this case, have cumulatively much higher than 95% of evidence identifying favor of the positive Lilly. Furthermore, Defendant regardless misuses the hypothetical in this setting. Professor Nesson emphasized: "Probability as we use the term in law, particularly in the civil standard of proof, is not a hard-edged mathematical concept. It is, rather, a concept that incorporates less rigid ideas of justice and reflects the judicial function of resolving disputes in the real world where values shift and knowledge is uncertain. An outcome is "probable" if it best accomplishes a just and acceptable resolution of the dispute. Probability as a legal concept in the law of proof, suggests wisdom, probity, and approbation—not favorable betting odds." Nesson, *Agent Orange Meets the Blue Bus: Factfinding at the Frontier of Knowledge*, 66 B.U.L.Rev. 521, 522, n.3 (1986).

attached to Levine Aff. In reality, Lilly's 25mg DES was the only DES product popularly available which was round, white, cross-scored, and without other markings. See Sparr Statement, App. 7; Sparr Study, App. 11; and Cafferty Statement, App. 12 attached to Levine Aff. No other commonplace DES therapy was available.

B. Squibb Is Not An Alternative

Lilly presents no evidence that Hingham's Pharmacy bought or stocked Squibb's DES pill, nor that anyone ever saw a Squibb DES product at the pharmacy. Most importantly, the Squibb pill is a non-alibi, because the mother's description of no markings other than the cross-score effectively rules out Stilbetin, which was imprinted with the "Squibb" emblem. See O'Leary Dep., p. 46, App. 19, attached to Levine Aff.; Squibb Pill, App. 8 (showing a faint "Squibb" imprint on the pill), attached to Levine Aff. Other conclusive evidence excluding Squibb is the mother ingested Stilbestrol, Squibb's pill was Stilbetin (App. 19, pg. 26, Squibb Pill, App. 8, attached to Levine Aff.), Squibb's pill was 100 mg, the prenatal records evidence the dosage starting at 12.5 mg and the mother testified she broke the pill making it possible to ingest the 100 mg dosage. (App. 8 and App. 14, attached to Levine Aff.) Finally, it is disputed whether Squibb's 100 mg DES pill even had white, cross-scored markings on it. Squibb denies it did. (App. 25, attached to Levine Aff.)

The great majority of decisions on this point have repeatedly ruled that summary judgment is improper on product identification when a mother describes a white, cross-scored DES pill that resembled the Lilly DES. In Kogen v. Eli Lilly, No., SACV 03-0962 (C.D. Cal., July 22, 2003), a mother remembered she took a white, cross-scored medicine for spotting but did not recall its name. Evidence was produced that the white-

cross scored medicine was DES, and that Lilly made such a pill. With much weaker evidence than presented here, the court ruled that evidence was credible and sufficient to go to the jury and summary judgment was denied. See Kogen Decision, App. 22, attached to Levine Aff.

In two other DES cases, Judge Martinez of the United States District Court in Seattle and Judge Sullivan of the United States District Court in D.C. in Woolfolk v. Eli Lilly and Co, et al., No. 2:03-cv-3577 (W.D.Wash., Mar. 15, 2005) and Brooks v. Eli Lilly and Co, et al., No. 1:03-cv-1796 (D.D.C. July 28, 2005) accepted the general "white cross-scored" description of the Lilly pill, the fact that the pill was taken to prevent a miscarriage, and evidence that Lilly's DES was routinely prescribed and dispensed in the area as sufficient triable issues of facts to defeat summary judgment. See Woolfolk Decision, App. 23; Brooks Order, App. 24, attached to Levine Aff.

Lilly is quick to point out their temporary victory in Bortell v. Eli Lilly & Co., No. Civ. A. 04-0954ESH, 2005 WL 3211719 (D.D.C. Oct. 20, 2005) (involving different issues of law on F.R.E. 807) and Galvin v. Eli Lilly & Co., No. 03-1797 (D.D.C. September 12, 2005) (concerning Rule 56(e) affidavits), currently in the Court of Appeals (of which Lilly fails to advise the Court in its memorandum).

Twenty years ago, the Seventh Circuit in McMahon, et al. v. Eli Lilly and Co., 774 F.2d 830 (7th Cir. 1985), gave Lilly the first of its many subsequent defeats. There, as here, the Plaintiff was unable to provide the written prescription or any record of whose DES she was exposed to. McMahon, 774 F.2d at 832. The manager of the relevant pharmacy could not remember any particular brand and could not negate Squibb or other brands. Id. Lilly presented two pharmacists who claimed that Squibb and other

brands were purchased by the pharmacy (something they have not ever tried in this case). McMahon, 774 F.2d at 833-34. Both testified that the Squibb pill was cheaper and would have been used. McMahon, 774 F.2d. at 834.

In Gassman v. Eli Lilly, No. 03-02592, mem. op. at *16 (D.D.C. Dec. 29, 2005), App. 17, attached to Levine Aff., this Court reaffirmed the McMahon decision and specifically ruled that the mother's description of the pill, along with a relevant pharmacist's testimony identifying Lilly as the exclusive DES dispensed, were sufficient to create a jury question and overcome summary judgment.

C. The Recent DES Product Identification Decision In Dunseth v Eli Lilly & Co. and Clayton v. Eli Lilly & Co. Sets The Bar For DES Identification Evidence

In Dunseth v. Eli Lilly & Co., Case No. 03-CV-02123, United States District Court for the District of Columbia, dated September 16, 2005, App. 16, attached to Levine Aff. Defendant Lilly filed a motion for summary judgment on the same DES identification issue. The plaintiff's mother there also recalled the description of the DES pill she took as white and cross-scored. A local Chicago area pharmacist, (but not stationed at the relevant store), Eugene Belczak, R.Ph., stated that the DES dispensed in that particular region could only have been Lilly's DES. The Dunseth Court denied Lilly's motion for summary judgment, stating:

> The Court finds that the description of the DES pills ingested by the plaintiff's mother, coupled with the affidavit of Eugene L. Belczak, create "an inference of probability" that the DES in question here was manufactured by the defendant.

Dunseth at 8.

Like Mr. Belczak's affidavit in Dunseth, Pharmacist Sparr's Statement, App. 7, attached to Levine Aff., coupled with Plaintiff's mother's definitive description and

identification of the Lilly's DES pill, should preclude summary judgment. The plaintiff in Dunseth had less of identification than Ms. Delaney, without a mother who had identified the Lilly pills from a photographic pill lineup, and still prevailed in summary judgment.

In Dunseth, as here, Lilly's entire case is based on the Blue and Red Book. Dunseth at *2. Judge Walton, however, ruled that,

> this factual dispute is genuine because it is supported by admissible evidence - the likely testimony of Mr. Belcazk and the plaintiff's mother ... Accordingly, this Court cannot conclude from the evidence before it that a reasonable juror could not find that the DES ingested by the plaintiff's mother was, in fact, manufactured by the defendant.

Dunseth at 9.

Similarly, in the most recent federal court decision in Clayton at 7, App. 18, attached to Levine Aff. Judge Urbina of the United District Court of the District of Columbia ruled that the reliability of a DES mother's visual identification of the DES pill from a photographic lineup only goes to the weight of the evidence and is for a jury to decide. The Zhang Affidavit, which is a review of nearly 300 DES pill photographs depicting 100 brands of DES that yielded no other pill matching the mother's description but for Eli Lilly's Diethylstilbestrol pill, was also taken into the court's consideration. See Clayton at 7, App. 18; Zhang Affidavit, App. 9, all of which are attached to Levine Aff. The court decided:

> Here, the plaintiff has met her burden because she submits evidence suggesting that: (1) the defendant is the only company that manufactured a 25 mg., white, cross-scored DES pill during the relevant time period and (2) the pharmacy where her mother filled her prescription dispensed the defendant's DES pills. The defendant, moreover, fails to point to any other manufacturers of 25 mg, white, cross-scored, DES pills who sold their products in the Birmingham area. Accordingly, the court denies the defendant's motion for summary judgment.

Clayton at 9, App. 18, attached to Levine Aff.

D. The Red and Blue Books Bear No Relevance To Any Material Facts In This Case

Pharmacist Sparr testified that in Boston during the 1960's to 1970's, pharmacies seldom bought generic drugs from the Red Book and Blue Book, as generics were unregulated, and generic companies were unknown and primarily regional operations particular to a certain locality, i.e. Lemoyne or Baltimore. See Sparr Statement, App. 7, attached to Levine Aff.

The Red and Blue Books are specialized and technical manuals and were offered in Defendant's motion without any foundation or expert substantiation. There is no evidence of whether the companies were distributors, manufacturers, bottlers, labelers or repackagers. It is beyond the purview of this Court or the average juror to interpret their meaning and import without some expert pharmacy guidance as to what they mean. Availability, distribution, marketing, labeling are all unexplained. Nowhere do these publications set forth a national market. See Sparr Statement and Sparr Study, App. 7 and 11, attached to Levine Aff. For example, Person & Covey only sold DES to California, Arizona, and Nevada, but never in Boston. See Person Dep., App. 13, attached to Levine Aff. The Red and Blue Books provides no information that Person & Covey's or anyone's DES could be bought in Boston.

While the Red Book and Blue Book mean nothing to the average juror, the "PDR" (Physicians' Desk Reference) is an accurate, well-known, and referenced text on available drugs and is sold in every bookstore. Lilly was the only DES manufacturer that maintained an advertisement in the 1969 PDR. See 1969 PDR, App. 20.

E. Harold Sparr, R. Ph. And Phillip J. Cafferty, R. Ph. Both Attest to Lilly's Dominance in the Boston DES Market. It is Factual and Scientific.

The Sparr survey study confirmed that Defendant Lilly possessed 94% of the DES market in 1969. See Sparr Study, App. 11, attached to Levine Aff. The Sparr Study meets criteria set forth from the "Reference Guide on Survey Research", Reference Manual on Scientific Evidence, 2d ed., (Fern M. Smith ed., Federal Judicial Center 2000, pp. 229-271). It complies with all of the standards regarding the design, administration and interpretation to ensure objectivity, representative sampling, avoiding bias, the relevant population and protection from influence. The survey was designed by the Boston University and carried out by an uninterested and impartial pharmacy information process. See Report of Hannelore Vanderschmidt, Ph.D., App. 21, attached to Levine Aff.

Mr. Philip Cafferty began his career in pharmacy in 1954, fifteen years before Plaintiff Julie Delaney was exposed. As a detailman for Lilly, he frequented doctors and drugstores to promote the Lilly product, all the while intermittently practicing retail pharmacy. Mr. Cafferty was ideally situated to address the practice of pharmacy over the last 50 years and the continuity of the predominance of Lilly products between the 1950s, 1960s and 1970s. Mr. Cafferty, with his experience in Indianapolis, the home of Lilly, and through the chain of marketing, promotion and delivery down to the 200 drugstores he physically observed in Boston and Rhode Island, was a unique expert in the field. He stated:

> Based upon my observations of drugstores and familiarity with the pharmaceutical field, Lilly had the lion's share, if not all of the DES market. I observed no other brand of DES in stores in Boston and Rhode Island in any meaningful

> quantity. With my experience and observations, it is inconceivable that I would not have seen it or heard of it, had it been there.

See Cafferty Statement, App. 12, attached to Levine Aff.

F. Lilly Admits That It Held Preferential Position In The DES Market.

Even before the DES tragedy was in the media, Lilly's Vice President testified before Congress that only three companies controlled the DES market and Lilly had 75% of that market. Dr. Thomas Carney, Vice President of Eli Lilly & Company testified in 1960:

> ...Mr. Mack: Doctor, is stilbestrol produced by most of the manufacturers, pharmaceutical manufacturers?
>
> Dr. Carney: No. I think stilbestrol is produced only by three companies in this country. Stilbestrol can be produced by anybody. It is an open compound.
>
> Mr. Mack: It is only produced by three manufacturers?
>
> Dr. Carney: Yes. As nearly as I know, three manufactures; yes, sir.
>
> Mr. Moss: What percentage of stilbestrol consumed in this country is produced by Eli Lilly?
>
> Dr. Carney: Maybe as high as 75 percent....

See Carney Testimony, App. 15, attached to Levine Aff.

V. PLAINTIFF WILLIAM DELANY HAS A VALID LOSS OF CONSORTIUM CLAIM

For reasons and evidence detailed above, there are genuine material facts in dispute on product identification such that a reasonable jury could find for the Plaintiff. As such, Plaintiff's ancillary claim for loss of consortium, which is a well-established cause of action in Massachusetts's law, could prevail at trial and summary judgment ought to be denied. Olsen v. Bell Labs. Inc., 388 Mass. 171, 176 (1983); Diaz v. Eli Lilly

& Co., 364 Mass. 153, 167-168 (1973). Although the female plaintiff's injury occurred before the marriage, it was never manifested nor appreciated until after the marriage. The injury affected the marriage and its very substantiality.

VI. CONCLUSION

Summary judgment is provided to avoid wasting everyone's resources if a trial would be a waste of time. This court could avoid that contingency by bifurcating a trial requiring product identification to be adjudicated first. The question before the Court is not, will the Plaintiff probably win at trial, but rather, could she possibly win? The state of the evidence before the Court, at this time, is too fact intensive and too controversial to warrant summary judgment.

For the reasons set forth, Defendant Lilly's motion for summary judgment should be denied.

Respectfully submitted,

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Dated: October 5, 2006

CERTIFICATE OF SERVICE

I, Erica Tennyson, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on October 5, 2006.

s/ Erica Tennyson
Erica Tennyson (BBO# 660707)